Human Brain Project

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Living up to privacy and informed consent in the Human Brain Project (HBP)

The Human Brain Project is an ambitious research and technology development project with social, ethical and philosophical implications. In this newsletter, recommendations for policy options on issues arising in relation to the HBP's construction of a multi-level data federation architecture for mental health data are given.

Edward Snowden's revelations of mass surveillance were an eye opener for publics and politicians alike: anyone can be the target of surveillance and the systems storing your personal data are vulnerable. Health data are an especially sensitive category of data. Anonymisation is therefore a central measure to protect the privacy of individuals. Additionally, informed consent is the basic principle guarding the use of personal data for research. However, informed consent can be difficult if not impossible to obtain for historic data.
During 2014, the Danish Board of Technology Foundation organised two stakeholder forums for researchers in the Human Brain Project's subproject 8, to discuss these issues with experts from law, social science and the humanities, data protection and the medical profession.[1]

Fears of misuse
The researchers in the Human Brain Project would like to federate historic data from hospitals. Data stored at the hospitals has at some point been collected from individuals. For medical research, the principle of informed consent dictates individuals' absolute right not to be involved in medical research, unless they have given their informed consent to participation. Several experts in the stakeholder

Policy options for the HBP Project:

- Clarify responsibilities: Who is responsible for data protection and security?
- Perform privacy impact assessment
- Follow 'good anonymisation practices' as laid out in EU Opinion 05/2014 on Anonymisation Techniques
- Make sure subcontractors follow good anonymisation techniques. Even better: avoid subcontracting
- Stamp data with the type of consent given
- Develop a partnering project on the privacy concerns in the Core Project
- Seek informed consent where at all possible
- Improve transparency and trust by:
    - Engaging in collaboration and dialogue with patient associations and external experts
    - Manage expectations by being realistic about outcomes and the research process to patients, medical professionals and the public
    - Listen to concerns and adapt accordingly

[1] The stakeholder forums were organized in collaborated with the HBP Foresight Lab at King's College London. The Danish Board of Technology Foundation and the HBP Foresight Lab are part of the HBP sub-project 12 'Society and Ethics'.

forums pointed out that people might object out of principle, or they might fear exposure and misuse of their private data.
The recent publicity disaster of the NHS' Care.data program is a case in point. Michael Reinsbourough from the HBP Foresight Lab explained how "People felt upset that they were opted-in to a data sharing scheme without proper information or an easy way to opt-out. For them this raised concerns about confidentiality, privacy and the commercialization of their personal information."
The experts agreed that a failure to seek informed consent, where at all possible, would most likely result in a serious public backlash to the HBP as well. As Professor of Ethics Thomas Ploug explained "Trust is a precondition of doing research. Trust decreases when you stop involving people and asking them for consent."

Several policy options were discussed. The participants agreed that the best route would be to get informed consent where at all possible. It could mean going back individuals (or families) to seek informed consent. Prospectively, researchers should ask for informed consent, and could possibly work with patient organisations on communication and patient involvement in research. A technical solution would be to "stamp" the data with the type of consent under which it had been given. This solution would make it possible to filter data according to national laws and regulations.

Good anonymization practices
In principle, anonymisation is a way to protect privacy. The problem is, that absolute anonymisation is practically impossible. The key concern is that data might be de-anonymised and used to identify and target individuals. At present all anonymisation techniques are vulnerable to 'singling out', 'linkability' or 'inference' attacks. Another option is a technique referred to as 'differential privacy'. The approach is robust against the three types of attacks. However, the technique is so designed that after a number of uses, data sets become 'toxic' privacy-wise, and they have to be destroyed.
The use of subcontractors poses another challenge to the data security and quality of the anonymisation procedure according to independent privacy advisor Caspar Bowden "They [subcontractors] might be looking for some kind of standard for anonymisation, but that does not exist, and the opinion 05/2014 explains why. The ones designing the anonymisation module have to read the opinion of the EU working party on anonymisation techniques, and you have to hit them over the head with it, again and again. Instead, approaches to anonymisation must be designed on a case-by-case basis."
The participants at the stakeholder seminars strongly advised to perform a 'privacy impact assessment'. Part of such an assessment would be to test the robustness of the anonymisation procedures with so-called "toy datasets" resembling the actual data.

Who is responsible?
In case of misuse of the hospital's data, it is important to know who is legally responsible, and who had access to the data. Richard Frackowiak, co-director of the HBP explained the HBP plans "The data are on the hospital servers, so we feel the best approach is for the hospitals to remain responsible for their data. In our HBP plan we do not aim to move the data from the hospital servers – they remain there governed by protocols and firewalls as presently. All we [HBP] plan to do is access pieces of data relevant to a particular research question, but then aggregate it in anonymised state before routing it temporarily to the researcher via a portal where similar samples will

Opinion 05/2014 on Anonymisation Techniques
On April 10 2014, the EU WP216 published an opinion on anonymization techniques. Three criteria are central when evaluating anonymisation techniques:

- is it still possible to single out an individual,
- is it still possible to link records relating to an individual, and
- can information be inferred concerning an individual?

K-anonymity for example, removes the risk of singling out, but not of linkability or inference. The WP recommends that the optimal anonymisation solution should be decided on a case-by-case basis. A solution (i.e. a complete anonymisation process) meeting the three criteria would be robust against identification performed by the most likely and reasonable means the data controller or any third party may employ. Whenever a proposal does not meet one of the criteria, a thorough evaluation of the identification risks should be performed.

In addition the opinion clarifies that pseudo-anonymisation is not an anonymisation technique.

come from many other hospitals for a final secondary aggregation. Anonymisation will be to the highest current industry standards that are in use. There is no ambition to identify individuals and this system really does anonymise." EU data protection law operates with the concept of a data controller. The law also makes room for the possibility of a co-controller. The multi-level data federation architecture of the HBP medical informatics platform makes question of legal responsibilities and co-controllership complex. The difficulty lies in determining the boundaries of responsibilities in a complex technical system. Dennis-Kenji Kipker, from the European Academy for Freedom of Information and Data Protection told, how "The problem is that if there are any leakages or problems with data security, then the MIP or the HBP can also be held reliable, as the HBP is responsible for developing the anonymisation procedure."

For the HBP, the legal entities in charge of signing contracts with the hospitals as well as with the subcontractors developing the anonymisation modules are unclear. The situation is further complicated by the different legislations in different countries, and the fact that EU data protection law is currently undergoing revisions. Dennis-Kenji Kipker explained "At the moment we have a very large grey area with regard to the system and legal entities." The lack of clarity on the legal status of the different entities involved in the date federation architecture is an acute problem.
Outsourcing presents several security risks as the contractors might not be as good as needed, sloppy with access to data or unaware of their responsibilities. Failure on the part of subcontractors could also fall back on the HBP itself. Caspar Bowden underlined the point "You really have to ask yourself - Do the contractors understand what they are doing? I am not aware of companies who can do this properly, possibly IBM and Microsoft."
Possible solutions could be to first and foremost seek clarification on legal responsibilities. A 'privacy officer' of the HBP could perform such a role. Secondly, responsibilities should be clearly communicated to the people in charge, as well as to the public. Finally, the participants advised to think carefully about the use of subcontracting, and to possibly try to avoid it altogether.

Transparency and trust
In the discussions with experts at the stakeholder forums, the issues of 'trust' and 'transparency' kept coming up. Both the external experts as well as the HBP researchers agreed that good communication on the process and goals of the planned research was absolutely crucial. Trust cannot just be reduced to a technical issue of good anonymisation practices or clarification of legal status. As Thomas Ploug explained "Issues of trust are not solely solved technically, you have to care about informed consent, transparency and communicate if the objectives are commercial or non-commercial." HBP co-director Richard Frackowiak agreed, and added, "I agree trust is many things such as informed consent, anonymization, transparency and dependency. We are privileged in that trust is good in the medical data field because major breaches or consequences are very few and far between."
In addition, trust is built by involvement, by listening and adapting to the needs of for example the patients groups targeted by the research of the HBP. One typical issue is the difference between outcomes for research and diagnostic outcomes for patients. While the data of individuals might together contribute to more knowledge that knowledge does not necessarily translate immediately to

Medical Informatics Platform (MIP) in the HBP
The HBP is a European initiative to understand the human brain and to enable advances in neuroscience, medicine and future computing. The researchers of the HBP have the ambition to redefine the understanding of brain diseases by studying the relationship between brain structure and function. The outcome would be a new way of categorizing diseases related to the brain.
The sub-project 8 (SP8) will build the Medical Informatics platform (MIP) for the HBP. The platform will provide tools for data-mining and rule-based clustering of the clinical data. The first goal of the Medical Informatics Platform Sub-Project is to federate hospital and other clinical data on all brain diseases and across multiple levels of biology.
The MIP will build on public and research databases, and hospital data, federated by novel data management and query techniques. This federation software and hardware will allow researchers to query and analyse a very large volume of data without moving them from local servers and without compromising data privacy.
Each participating hospital will be requested to build a local data warehouse. This will allow data to be accessed and interrogated by the MIP in the most efficient and secure manner, fully maintaining its accuracy, consistency and privacy.

improved diagnosis or treatments for those patients. It is important for trust to emerge that a mismatch of expectations is avoided. Dianne Gove from Alzheimer Europe "I am very interested to report this back to people with dementia and their carers. There are obviously a lot of issues on anonymisation and trust, but also on promoting autonomy and promoting participation with people with dementia and their caretakers in research. I am very enthusiastic about collaboration."
To get started with the building of trust and the development of a transparent and adaptive approach, the HBP might seek inspiration in models for collaborations with patients developed by others. As an example, recent studies with Parkinson patients in the UK have showed that engagement with the patients through patient organisations has increased the uptake of patients in research projects.[2]

[2] Patientsinresearch.org

This newsletter is written and edited by DBT director Lars Klüver and DBT project manager Lise Bitsch. We are grateful for comments from HBP Foresight Lab at King's College London. We are deeply grateful to Bernd Stahl, for stepping in as moderator of the seminar. We would also like to thank the participants at our seminar, for their efforts and dedication to the discussions in the seminar. While every caution has been taken to represent the views of the participants quoted in this newsletter accurately, the final representation remains the responsibility of the author(s). The views and opinions expressed in this newsletter may not be taken as those of the Human Brain Project or any of its sub-projects.

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Stakeholder Forums 2014
In 2014, The Danish Board of Technology Foundation organised a number of dialogues between researchers from HBP's medical informatics work package, and external stakeholders. The theme for the first year was "Multi-level brain data federation and data protection" and "Development of 'disease signatures' and personalised medicine". For our first year activities we collaborated with the HBP Foresight Lab at King's College London. For our Webinar, Nikolas Rose, leader of the HBP Foresight Lab, provided comments for discussion and reflection. For the seminar on Multi-level data federation and disease signature and personalized medicine, the Foresight lab provided a 'scoping report' with scenarios of plausible future controversies. The Danish Board of Technology Foundation and the HBP Foresight Lab are part of the HBP subproject 12 'Society and Ethics'.